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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,379	11/17/2003	Tony Hunter	066671-0085	4384
54244	7590	03/27/2006	EXAMINER	
KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET SUITE 1600 PORTLAND, OR 97204			YAO, LEI	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/716,379

Applicant(s)

HUNTER ET AL.

Examiner

Lei Yao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4,9,10,16,17,20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,9,17 and 20 is/are rejected.
- 7) ☒ Claim(s) 10,16 and 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/30/05</u>   | 6) <input type="checkbox"/> Other: _____                                    |

***DETAILED ACTION***

The Amendment filed on 1/26/06 in response to the previous Non-Final Office Action (10/04/05) is acknowledged and has been entered.

Claims 1-3, 5-8, 11-15 and 18-19 have been cancelled. Claims 4, 9-10, 16 and 17 have amended. Claims 20-21 have been added. Claims 4, 9-10, 16-17, 20-21 are under consideration.

**The text of those sections of Title 35, U.S.Code not included in this action can be found in the prior Office Action.**

**Information Disclosure Statement**

The information disclosure statement (s) (IDS) submitted on 9/30/05 are/is considered by the examiner and initialed copy of the PTO-1449 is enclosed.

**Rejections Withdrawn**

1. The rejection of claims 4 and 7-19 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the cancellation and amendments to the claims.

**Claim Objections**

Claims 10, 16, and 21 are objected to as being dependent upon a rejected base claim 4, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Response to Arguments**

***Rejection under 35 USC § 112 1<sup>st</sup> paragraph-- Drawn to written description***

The rejection of claims 4, 9, 17 and 20 are rejected under 35 U.S.C. 112 first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for the reasons of record in the prior Office Action (10/4/05, page 3-5) and made again for the newly amended claims above and newly added claim 20.

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Please note the claims 10 and 16 have been withdrawn from this rejection in view of the amendments to the claims.

The response filed 5/10/05 has been carefully considered but is deemed not to be persuasive. The response states that applicants have amended the claims, which the claimed genus of method involves a specific Pin1 protein having a SEQ ID NO: 2 and its functional fragments having protein-protein interaction activity and/or peptidyl prolyl isomerase activity (PPI). The response also argues that Applicants have provided the complete structure of the protein (SEQ IDNO: 2) from which all recited fragment derive and specification provides a description of a representative number of species of "a Pin 1 protein having the amino acid sequence set forth in SEQ IDNO: 2 or a functional fragment ... [having ] protein-protein interaction activity and/or PPI activity' for use in the claimed method.

In response to this argument, newly amended claims are amended by adding the SEQ ID NO: 2 in the claims, and are reciting a method for determining whether a composition inhibits the activity of the Pin1 by incubating the composition with Pin 1 protein (SEQ ID NO: 2) or a function fragment thereof, wherein the functional fragment of the Pin 1 protein has protein-protein interaction activity and/or PPI activity. Thus, the claims are inclusive of a genus of functional fragments, which have a protein-protein interaction activity. The specification, on page 4, paragraph 2 and figure 2, teaches that Pin protein has a WW domain, which mediates protein-protein interaction. The specification further teaches that Pin 1 protein interacts with NIMA protein kinase and inhibits NIMA-induced activity (example 5, page 35-37 and example 7, page 39-40). However, the specification has not provided any examples to show or any other protein other than NIMA protein kinase, which could interact with Pin protein or functional fragment.

As stated in the previous Office action, "A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the

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genus." The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., \_\_\_ F.3d \_\_\_, 2004 WL 260813, at \*9 (Fed.Cir.Feb. 13, 2004).

The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification does not provide a representative number of proteins, which could interact with Pin 1 protein or functional fragments, in which their activities are modulated by a composition. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of one NIMA protein that interacts with Pin1 or WW domain of Pin 1 protein is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed. Therefore, only the Pin1 protein (SEQ ID NO: 2) a functional fragment of Pin 1 (SEQ ID NO: 2) that interacts with NIMA protein kinase, which is modulated by a composition, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph.

### **Conclusion**

NO claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.  
Examiner  
Art Unit 1642

LY

  
SHEELA HUFF  
PRIMARY EXAMINER